PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
A01018M		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP00/00355	25/01/2000	25/01/1999
International Patent Classification (IPC) or national classification and IPC G06F19/00		
Applicant INSTITUTE OF MEDICINAL MOLECULAR DESIGN et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 9 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
14/06/2000	24.04.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Platzer, C Telephone No. +49 89 2399 2462

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/JP00/00355

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-39 as originally filed

Claims, No.:

1-16 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 1,12,13.

because:

☒ the said international application, or the said claims Nos. 1,12,13 relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	2-5,7-9,11,14-16
Inventive step (IS)	Yes:	Claims	
	No:	Claims	6,10
Industrial applicability (IA)	Yes:	Claims	2-11,14-16

No: Claims

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. Claim 12 defines a data record on a media including at least
   - its identifier;
   - a gap information;
   - identifiers of sequences in a sequence information.

   Such a data record merely comprises data encoding cognitive content in a standard manner. The three elements of the record cannot be regarded as functional data defined in terms which inherently comprise the technical features of the system in which the carrier is operative.
   Claim 12 therefore relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(v) PCT. Consequently, no opinion will be formulated with respect to novelty, inventive step and industrial applicability of the subject-matter of claim 12 and dependent claim 13 (Article 34(4)(a)(i) PCT).

1.1 Claim 1 correspondingly defines a description method which separates an alignment information into a sequence information and a gap information.
This is considered to represent a pure abstract idea without any technical context, therefore the subject-matter defined in claim 1 also falls under the list of items set out in Rule 67.1 PCT for which no preliminary examination shall be carried out.

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

2. Reference is made to the following documents:

D1: Stoesser G., Tuli M.A., Lopez R. and Sterk (1999) The EMBL Nucleotide Sequence Database. *Nucleic Acids Res.*, **27**, 18-24

D2: Thompson J., Higgins D., Gibson J. (1994) CLUSTAL W: improving the sensitivity of progressive multiple sequence alignment through sequence weighting, position-specific gap penalties and weight matrix choice. *Nucleic Acids Res.*, **24**, 4673-4680

2.1 The documents D1 and D2 were not cited in the international search report. A copy of the documents is appended hereto.

3. The present application does not meet the requirements of Articles 33(1) PCT, because the subject-matter of claim 2 is not novel in the sense of Article 33(2) PCT.

3.1 Claim 2 defines a storing method for amino-acid or nucleic-acid sequence information which is based on the separation of an alignment information into a sequence information and a gap information expressing correspondence between sequences.

Storing methods which separate sequence information from "gap information" as claimed are well known in the prior art.
D1 relates to the EMBL Nucleotide Sequence Database which is maintained and distributed at the European Bioinformatics Institute (EBI).
Database entries are stored in a particular format which inter alia comprises an accession-number being used for identifying the different database entries.
The EMBL Database also permits the insertion of "unfinished" sequences in several phases (HTG PHASES), where sets of sequence pieces are entered,

each sequence being indexed and located in terms of its base pair number (see D1, page 20, section "Unfinished HTG data").
This situation is a full anticipation of the features included in claim 2: The sequence information is given in the body of the entry corresponding to the accession number and the feature identifiers in the header of the entry identifying each contiguous sequence piece can be regarded as the gap information expressing the correspondence between sequences in the sense of claim 1.
The correspondence is clearly expressed in terms of the locations in the sequence chain.
Thus, claim 2 is completely anticipated by D1 and therefore lacks novelty.

3.2 It should be noted that for the comparison of paragraph 3.1 above the term "alignment" was interpreted to stand for "the appropriate or expected relationship of one thing to another or others", which certainly encompasses the relationship between two sequences within a larger piece of data, as described in D1.
D1 however does not explicitly describe how sequence data of the EMBL database is **compared** to new DNA data.
However, even a clarification to that end would not render the claim inventive, since it is considered to be perfectly clear to the skilled person that once sequence and gap information are established for the items to be compared, they will certainly be used in the process of finding correspondences between the sequences concerned.
Such a (hypothetical) claim would then lack an inventive step as required by Articles 33(3) PCT.

4. The communication method defined in claim 9 fully corresponds to the storing method of claim 2 and is therefore also anticipated by the disclosure of D1, since the storing process necessarily comprises the communication of the data to the data carrier.

5. As to the determination of a unique identifier of an alignment information, any sequence piece entered as unfinished HTG data in the EMBL Nucleotide Sequence Database is certainly uniquely identifiable through accession number and indication of base sequence range within the record.
Claim 11 is therefore also anticipated by D1.

6. Dependent claims 3-8, 10 and 14-16 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty or inventive step, the reasons being as follows:

Claims 3-5 and 7,8 and 14-16 only define straightforward implementation details directly derivable from the disclosure of D1;

Claim 6 defines the reference to residue numbers of another sequence for the description of gap information which is not explicitly disclosed in D1. However, as already set out in paragraph 3.2 above, a skilled person would certainly consider the "exploitation" of the gap information description already known from D1 such that duplication of information storage is avoided. This leads directly to the solution of using residue numbers of another sequence as defined in claim 6. Claim 6 therefore lacks an inventive step (Articles 33(1) and (3) PCT).

7. Concerning the removal of redundancies of the sequence information prior to communication as defined in claim 10 it should be noted that this feature merely states a principle well known in the field of telecommunications: the efficient use of the bandwidth of any transmission channel can be improved by removing redundancies in the data to be transmitted. The application of this concept to biotech data is considered to be straightforward.

Re Item VII

Certain defects in the international application

8. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D2 is not mentioned in the description, nor are these documents identified therein.

9. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

Re Item VIII

Certain observations on the international application

10. Claim 9 includes the expression:

"..the communication of the gap information at least out of the informations"

which does not seem to make sense, since it remains unclear how information can be communicated "out of the informations".
Claim 9 therefore violates the provisions of Article 6 PCT.